

AUG 31 2000

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601

Phone: (949) 250-3959
Fax: (949) 250-3210

The arrhythmia detection function added to the BSM-1102 device has been classified as Class III per the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025, "Physiological Patient Monitor with Arrhythmia Detection and Alarms," per MHX. The remaining functions of the device have been classified as Class II by the Cardiovascular Device Classification Panel under 21 CFR Part 870.2300, "Cardiac Monitor (including cardiometer and rate alarms)," per DRT; under 21 CFR 870.1110 and 870.1100, "Blood pressure computer and alarm," per DSK and DSJ; under 21 CFR 870.2700, "Oximeter," per DQA; under 21 CFR 870.1130, "Noninvasive Blood Pressure Measurement System," per DXN; under 21 CFR 870.2910, "Radio Frequency Physiological Signal Transmitter," per DRG, by the Anesthesiology Device Classification Panel under 21 CFR 868.2375, "Breathing Frequency Monitor," per BZQ and under 21 CFR 868.1400, "Carbon Dioxide Gas Analyzer," per CCK, and by the General Hospital and Personal Use Classification Panel under 21 CFR 880.2910, "Electronic Clinical Thermometer," per FLL.

Common names for the BSM-1102 device include Patient Monitor, Portable Monitor, Transport Monitor, Cardiac Monitor, Bedside Monitor.

The predicate marketed device is the Nihon Kohden BSM-8800A LifeScope 14 Bedside Monitor per 510(k) # K920154, commercial distribution certification dated 12/18/92.

Nihon Kohden's BSM-1102 Patient Monitor is intended to monitor, record and display the electrocardiogram and produce a visible or audible signal or alarm when a ventricular arrhythmia exists. The device also monitors, displays and records heart rate, pulse rate, blood oxygen saturation (SpO₂), noninvasive blood pressure (NIBP), invasive blood pressure (IBP), CO₂, respiration and temperature and sound alarms when a measured rate falls outside preset limits. This device may also be used to condition and transmit physiological signals via radio frequency. This device will be available for use by medical personnel on all patient populations within a medical facility.

The device complies with IEC 601-1 subclause 56.3(c) as implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. No other special controls or performance standards are known or established for this device.

The BSM-1102 device is not sterile.

The device does not directly contact patients. Accessories that contact patients, such as thermistors, are the same accessories as used with other legally marketed products or are comprised of the same component materials as the predicate accessories. Therefore, good laboratory practice studies were not required per 21 CFR part 58.

The BSM-1102 LifeScope EC was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of acquiring, processing, displaying and recording of all functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the BSM-1102 Patient Monitor is substantially equivalent to the Nihon Kohden BSM-8800A LifeScope 14 Bedside Monitor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Ms. Bonnie Bishop
Regulatory Affairs Manager
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, California 92612-1601

Re: K000517
Nihon Kohden BSM-1102 LifeScope EC and accessories
Regulatory Class: III (three)
Product Code: 74 MHX
Dated: May 12, 2000
Received: May 15, 2000

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

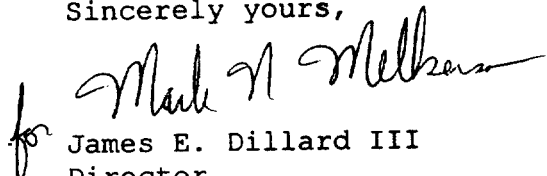
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition,

FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K000517

Device Name: BSM-1102 LifeScope EC

Indications for Use:

The BSM-1102 Patient Monitor is intended to monitor the electrocardiogram and produce a visible or audible alarm when a ventricular arrhythmia exists. The device also monitors, displays and records heart rate, blood oxygen saturation (SpO₂), noninvasive blood pressure (NIBP) or invasive blood pressure (IBP), CO₂, EtCO₂, respiration rate and temperature and sound alarms when a measured rate falls outside preset limits. The device may also be used to condition and transmit physiological signals via radio frequency.

The BSM-1102 Patient Monitor will be available for use by medical personnel on all patient populations within a medical facility.

for Mark N. Melkerson
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
Neurological Sciences
510(k) Number K000517